49

113 (new). A method for storing human neonatal or fetal hematopoietic stem cells derived from the blood, said method comprising cryopreserving human neonatal or fetal blood components containing human neonatal or fetal hematopoietic stem cells from the umbilical cord blood or placental blood of a single human collected at the birth of said human, such that the cells remain viable, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult.

50 114 (new). The method of claim 113, wherein said blood components comprise whole blood.

51 115 (new). The method of claim 113, wherein said cryopreserving comprises adding a cryoprotective agent to said cells.

52 116 (new). The method of claim 115, wherein said cryoprotective agent is dimethyl sulfoxide.

53 117 (new). The method of claim 113, 114, 115 or 116, wherein said cryopreserving comprises storing said cells in liquid nitrogen or its vapor.

54 118 (new). The method of claim 113, 114, 115 or 116, further comprising adding an anticoagulant to said cells.

55 119 (new). The method of claim 113, 114, 115 or 116, further comprising enriching the cells by a cell separation procedure.

56 120 (new). The method of claim 113, 114, 115 or 116, further comprising growing the cells *in vitro*.

REMARKS

Claims 60-62, 67-102 and 104-120 will be pending and under consideration in the present application upon entry of the present Supplemental Reply.

Claims 113-120 have been added. Support for newly added claims 113 and 114 is found throughout the specification as filed, *inter alia* at page 25, lines 6-21; page 36, lines 19-20; and at page 98, lines 14-15 and line 34. Claims 115 and 116 are supported at page 43, line 36 to page 44, line 5. Claim 117 is supported at page 46, lines 8-10. Claim 118 is supported at page 26, line 1, claim 119 is supported at page 36, line 22, and at page 37, line 1 to page 38, line 6. Claim 120 is supported at page 43, lines 4-22.

No new matter is added by the amendments made herein.

CONCLUSION

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. Claims 60-62, 67-102 and 104-112 fully meet all statutory requirements for patentability. Allowance and action for issuance are respectfully requested.

Applicants request that the Examiner call Adriane M. Antler at (212) 790-2247 if any questions or issues remain.

Respectfully submitted,

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EXHIBIT A

Serial No.: 08/442,277
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PENDING CLAIMS WITH AMENDMENTS MADE AS OF MARCH 25, 2002

60. A method for treating a human patient in need of hematopoietic reconstitution comprising introducing into the human patient a composition comprising a cryoprotective agent and human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human so as to provide hematopoietic reconstitution.

61. The method according to claim 60 in which the composition further comprises human neonatal or fetal hematopoietic progenitor cells derived from the blood.

62. The method according to claim 60 in which the composition comprises whole neonatal or fetal blood.

67. The method according to claim 60 in which the patient has a failure or dysfunction of normal blood cell production and maturation.

68. The method according to claim 67 in which the patient has anemia.

69. The method according to claim 60 in which the patient has a hematopoietic malignancy.

70. The method according to claim 69 in which the hematopoietic malignancy is a leukemia.

71. The method according to claim 69 in which the hematopoietic malignancy is a lymphoma.

72. The method according to claim 60 in which the patient has an autoimmune disease.

73. The method according to claim 60 in which the patient has a genetic disorder.

74. The method according to claim 60 in which the patient is immunodeficient.

75. The method according to claim 74 in which the immunodeficiency is by reason of irradiation.

76. The method according to claim 74 in which the immunodeficiency is by reason of chemotherapy.

77. The method according to claim 74 in which the immunodeficiency is by reason of infection by a pathogenic microorganism.

78. The method according to claim 74 in which the patient has a malignant solid tumor.

79. The method according to claim 60 in which the patient has Fanconi's anemia.

80. The method according to claim 60 in which the patient has a hypoproliferative stem cell disorder.

81. The method according to claim 60 in which the patient is infected by a pathogen.

82. A method for treating a human patient in need of hematopoietic reconstitution comprising:

(a) obtaining human neonatal or fetal blood components comprising hematopoietic stem cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human;

(b) cryopreserving the blood components;

(c) thawing the blood components; and

(d) introducing the blood components into the human patient so as to provide hematopoietic reconstitution.

83. The method according to claim 82 in which the stem cells are autologous to the patient.

84. The method according to claim 82 in which the stem cells are syngeneic to the patient.

85. The method according to claim 82 in which the stem cells are allogeneic to the patient.

86. The method according to claim 82 in which the blood components comprise whole blood.

87. The method according to claim 82 in which the blood components are isolated by collection from an umbilical cord.

88. The method according to claim 82 in which the blood components are isolated by collection from a placenta.

89. The method according to claim 82 in which the patient is immunodeficient.

90. The method according to claim 89 in which the immunodeficiency is by reason of irradiation.

91. The method according to claim 89 in which the immunodeficiency is by reason of chemotherapy.

92. The method according to claim 89 in which the immunodeficiency is by reason of infection by a pathogen.

93. The method according to claim 89 in which the patient has a malignant solid tumor.

94. The method according to claim 82 in which the patient has anemia.

95. The method according to claim 94 in which the patient has Fanconi's anemia.

96. The method according to claim 82 in which the patient has a hypoproliferative stem cell disorder.

97. The method according to claim 82 in which the patient has a hematopoietic malignancy.

98. The method according to claim 97 in which the hematopoietic malignancy is a leukemia.

99. The method according to claim 97 in which the hematopoietic malignancy is a lymphoma.

100. The method according to claim 82 in which the patient has an autoimmune disease.

101. The method according to claim 82 in which the patient has a hemolytic disorder.

102. The method according to claim 82 in which the patient has a genetic disorder.

104. A method for treating a human patient in need of hematopoietic reconstitution comprising:

(a) obtaining human neonatal or fetal blood components comprising hematopoietic stem and progenitor cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human;

(b) cryopreserving the blood components;

(c) thawing the blood components; and

(d) introducing the blood components into the human patient so as to provide hematopoietic reconstitution.

105. The method according to claim 104 in which the stem and progenitor cells are autologous to the host.

106. The method according to claim 104 in which the stem and progenitor cells are syngeneic to the host.

107. The method according to claim 104 in which the stem and progenitor cells are allogeneic to the host.

108. The method according to claim 107 in which the host has Fanconi's anemia.

109. The method according to claim 104 in which the blood components are isolated by collection from an umbilical cord.

110. A method for treating a human patient in need of hematopoietic reconstitution comprising introducing into the human patient a composition comprising human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or

placental blood of a human collected at birth of said human, in which the stem cells have been previously cryopreserved, so as to provide hematopoietic reconstitution.

111. The method according to claim 60 in which the stem cells are from the umbilical cord blood or placental blood of a single human collected at the birth of said human.

112. A method for treating a human patient in need of hematopoietic reconstitution comprising (a) thawing cryopreserved blood components comprising human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human; (b) and introducing the thawed blood components into the human patient so as to provide hematopoietic reconstitution.

113. A method for storing human neonatal or fetal hematopoietic stem cells derived from the blood, said method comprising cryopreserving human neonatal or fetal blood components containing human neonatal or fetal hematopoietic stem cells from the umbilical cord blood or placental blood of a single human collected at the birth of said human, such that the cells remain viable, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult.

114. The method of claim 113, wherein said blood components comprise whole blood.

115. The method of claim 113, wherein said cryopreserving comprises adding a cryoprotective agent to said cells.

116. The method of claim 115, wherein said cryoprotective agent is dimethyl sulfoxide.

117. The method of claim 113, 114, 115 or 116, wherein said cryopreserving comprises storing said cells in liquid nitrogen or its vapor.

118. The method of claim 113, 114, 115 or 116, further comprising adding an anticoagulant to said cells.

119. The method of claim 113, 114, 115 or 116, further comprising enriching the cells by a cell separation procedure.

120. The method of claim 113, 114, 115 or 116, further comprising growing the cells *in vitro*.